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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,079	09/04/2001	Atsushi Suzuki	213502US0	1164

22850 7590 07/13/2004

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EXAMINER	
COE, SUSAN D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,079	SUZUKI ET AL.	
	Examiner	Art Unit	
	Susan D. Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2004 and 31 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9 and 11-31* is/are pending in the application.

4a) Of the above claim(s) *15-18 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9, 11-14, 19-29, and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 31, 2004 has been entered.

2. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

3. Claims 6-9 and 11-31 are pending.

Election/Restrictions

4. In Paper No. 6, dated February 19, 2002, applicant elected with traverse Group II, claim 6, now including claims 7, 8, 9, and 11-31, chlorogenic acid for species A, and organic acid having a molecular weight of 60 to 300 for species B. Lactic acid was selected as the species examined for B.

5. Claims 15-18 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, i.e. they do not specifically contain the elected species of lactic acid, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

6. Claims 6-9, 11-14, 19-29, and 31 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6-9, 11-14, 19-29, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the claims requires that the chlorogenic acid is present in an amount from 0.001 to 10 wt%. However, the specification only provides support for including this compound in amounts from 0.001 to 5% (see pages 7 and 8 of the specification). Thus, the percentages between 5% and 10% are not considered to be supported by the disclosure; therefore, these new limitations constitute new matter.

Claim Rejections - 35 USC § 103

8. Claims 6-9, 11-14, 19-29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (Chinese Pharm. Journal 91994), vol. 46, no. 6, pp. 575-582) and US Pat. No. 4,981,852 for the reasons set forth in the Office action of November 4, 2003.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not deemed persuasive. Applicant argues that Cheng does not teach combining chlorogenic acid with an organic acid. In addition, applicant argues that US '852 does not specifically teach combining lactic acid with chlorogenic acid. However, the references

taken together are considered to teach the claimed invention. Both references teach that compositions comprising chlorogenic acid and lactic acid are known to treat hypertension. It is well established that it is obvious to combine two or more ingredients that are both known to be useful for the same purpose. Thus, since the prior art taken as a whole teaches that both claimed ingredients are used in compositions to treat hypertension, a person of ordinary skill in the art would be motivated to combine the two disclosed compositions together.

Applicant also argues that US '852 does not specifically teach that lactic acid itself has antihypertensive properties. Applicant points out that the reference uses the lactic acid to solubilize the active antihypertensive ingredient. However, applicant's claims use the broad transitional phrase "comprising" which allows for the inclusion of additional ingredients in the composition. A person of ordinary skill in the art would be motivated to use the entire antihypertensive composition taught by US '582 because the entire composition together treats hypertension. Thus, an artisan of ordinary skill would be motivated to combine the compositions of the references together. This would lead to a composition that comprises lactic acid and chlorogenic acid.

In regards to applicant's new limitations regarding ingredient amount, the references do not specifically teach adding the ingredients in the amounts claimed by applicant. However, both references do teach that the amount of each ingredient can be varied (see claim 10 of US '582 and Table 1 of Cheng). Thus, the amount of each specific ingredient in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill

to determine the optimal amount of each ingredient to add in order to best achieve the desired antihypertensive results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 6-9 and 19-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-6, 10-16, and 30-39 of copending Application No. 09/922,694. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 09/922,694 are drawn to administering chlorogenic acid to treat hypertension. The chlorogenic acid is administered with caffeic acid and ferulic acid both of which are organic acids with a molecular weight between 60 and 300. The claims of 09/922,694 do not specifically claim using the ingredients in the amounts claimed. However, as discussed above, it is considered obvious to modify the amount of ingredient amounts in pharmaceutical compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 6-9, 11-14, 19-29, and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-6, 10-16, and 30-39 of copending Application No. 09/922,694 in view of US Pat. No. 4,981,852.

As discussed above, 09/922,694 claims using chlorogenic acid to treat hypertension. However, the application does not specifically claim combining the chlorogenic acid with the elected species of lactic acid.

US '852 teaches using a composition comprising lactic acid to treat hypertension (see claims).

These references show that it was well known in the art at the time of the invention to use chlorogenic acid and an organic acid to treat hypertension. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the two substances would also be useful in treating hypertension. Therefore, the artisan would have been motivated to combine chlorogenic acid and an organic acid together to treat

hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references do not specifically teach using the ingredients in the amount claimed by applicant; however, as discussed above, this modification of ingredient amount is considered to be an obvious modification of parameters.

This is a provisional obviousness-type double patenting rejection.

11. Claims 6-9 and 19-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-16 of copending Application No. 10/632,810 or copending Application No. 10/826,289. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 10/632,810 and 10/826,289 are drawn to administering chlorogenic acid to treat hypertension. The chlorogenic acid is administered with ferulic acid which is an organic acids with a molecular weight between 60 and 300. The claims of 10/632,810 and 10/826,289 do not specifically claim using the ingredients in the amounts claimed. However, as discussed above, it is considered obvious to modify the amount of ingredient amounts in pharmaceutical compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 6-9, 11-14, 19-29, and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-16 of copending Application No. 10/632,810 or copending Application No. 10/826,289 in view of US Pat. No. 4,981,852.

As discussed above, 10/632,810 and 10/826,289 and claim using chlorogenic acid to treat hypertension. However, the application does not specifically claim combining the chlorogenic acid with the elected species of lactic acid.

US '852 teaches using a composition comprising lactic acid to treat hypertension (see claims).

These references show that it was well known in the art at the time of the invention to use chlorogenic acid and an organic acid to treat hypertension. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the two substances would also be useful in treating hypertension. Therefore, the artisan would have been motivated to combine chlorogenic acid and an organic acid together to treat hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references do not specifically teach using the ingredients in the amount claimed by applicant; however, as discussed above, this modification of ingredient amount is considered to be an obvious modification of parameters.

This is a provisional obviousness-type double patenting rejection.

13. Claims 6-9, 11-14, 19-29, and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of copending Application No. 10/810,611 in view of US Pat. No. 4,981,852.

10/810,611 claims using esters of chlorogenic acid to treat hypertension. However, the application does not specifically claim combining the chlorogenic acid with the elected species of lactic acid.

US '852 teaches using a composition comprising lactic acid to treat hypertension (see claims).

These references show that it was well known in the art at the time of the invention to use esters chlorogenic acid and an organic acid to treat hypertension. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination

of the two substances would also be useful in treating hypertension. Therefore, the artisan would have been motivated to combine esters of chlorogenic acid and an organic acid together to treat hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references do not specifically teach using the ingredients in the amount claimed by applicant; however, as discussed above, this modification of ingredient amount is considered to be an obvious modification of parameters.

This is a provisional obviousness-type double patenting rejection.

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan D. Coe

Susan D. Coe, Examiner
July 2, 2004